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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,989	12/13/2000	Johan H. Geerke	ARC2940R1	5705

7590

09/09/2002

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EXAMINER

DEWITTY, ROBERT M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,989

Applicant(s)

GEERKE, JOHAN H.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13-15 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 and 22-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9, 13-15 are pending in the instant application. Claims 16-21 are cancelled. Acknowledgement is made of Applicant's response submitted 6/22/02.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-9, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magruder et al. (U.S. Pat. No. 5,630,808).

Magruder teaches a delivery system for delivering a dosage unit amount of a drug to a warm-blooded animal. The delivery system can take the form of a first wall section surrounds an internal space occupied by a beneficial agent formulation (col. 10, lines 26-31). The system also includes a second wall section comprising a composition that aids in controlling fluid flux into the compartment area (col. 11, lines 1-5). After assembly of the delivery system, a passageway is laser drilled into the end of the system for delivering the beneficial agent (col. 18, lines 18-20). Because Magruder teaches a passageway drilled through the lead end of the system (col. 18, lines 18-24), it is examiner's view that the second wall section (positioned at the posterior of the system) remains intact.

2. Claims 1-9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magruder, further in view of Theeuwes et al. (U.S. Pat. No. 4,088,864).

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As stated above, Magruder refers to a delivery system comprised of a first wall, a second wall, a beneficial agent contained in the interior and an exit passageway made by a laser. However, Magruder does not refer to a specific type of laser for making the passageway.

Theeuwes teaches making passageways using lasers. CO₂ lasers are taught to be more efficient for using as opposed to lasers with higher or lower wavelengths (col. 4, lines 30-34).

Based on the teachings of Theeuwes that CO₂ lasers are suitable for use in forming passageways, and Magruder's teaching that a laser can be used to form passageways, one with ordinary skill in the art would have been motivated to use CO₂ lasers to form the passageway in the delivery system of Magruder.

Response to Arguments

3. Applicant's arguments filed 6/22/02 have been fully considered but they are not persuasive.

Applicant asserts that the teachings of Magruder fail to suggest a dosage form That has an outer wall defining an interior compartment with a barrier layer disposed between the outer wall and the interior compartment. In response, the examiner below has listed the teachings of Magruder as compared with the instant invention.

Magruder's invention

-A first wall section

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-Surrounding an internal space

With a beneficial agent

-A second wall section that aids in controlling

fluid flux

As shown in the figures of Magruder (notably figures 10 and 11) the second wall is disposed between the first wall and the internal space. Therefore, the rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

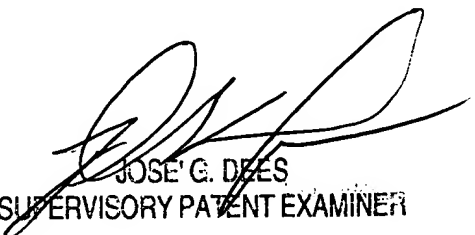
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
September 3, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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